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EXAMINER

PATEL, SHEFALI DILIP

ART UNIT

PAPER NUMBER

3767

NOTIFICATION DATE

DELIVERY MODE

11/17/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/565,734

Applicant(s)

RODD, AARON

Examiner

SHEFALI D. PATEL

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgments

1. In the reply, filed on August 23, 2008, Applicant cancelled claim 17.
2. Examiner objected to claims 1, 2, and 18 for minor informalities. Applicant amended the claims to address the noted concerns. Objections are withdrawn.
3. Examiner rejected claim 18 under 35 USC 112, 2nd paragraph for indefiniteness in relation to whether the stated “release means” belonged to the “end member” or to the “needle holder”. Applicant corrected the limitation as “release means of the end member”. Rejection is withdrawn.
4. Currently, claims 1-16 and 18 are under examination.

Response to Arguments

5. Applicant’s arguments, see pages 8-9, filed on August 23, 2008, with respect to claims 1, 2, 5-16, and 18 rejected under Barker et al (US 6,569,115), have been fully considered and are persuasive. The rejection of June 6, 2008, has been withdrawn.
6. Applicant’s arguments filed on August 23, 2008, with respect to claims 1, 2, and 4-18 rejected under Shue et al (US 6,921,386) have been fully considered but they are not persuasive:

Applicant argues that Shue et al does not teach that the end member comprises sealing means that sealing engage with the inner tubular member together with release means moveable between first and second positions to lock the end member to, and to unlock the end member from, the inner tubular member (page 9). However, Shue et al

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does teach that the end member (seal member [43]) comprises sealing means that sealing engage with the inner tubular member (plunger [4]) together with release means (sealing portion [434] and segment [433]) moveable between first and second positions to lock the end member to (Figures 4-6), and to unlock the end member from (Figures 8 and 11), the inner tubular member (column 5, lines 44-59). Release means [434][433] are released so that the end member [43] can retract and move distally further into the inner tubular member [4] (i.e. first position to second position).

Applicant argues that Shue et al does not teach release means on the needle holder that are moveable between first and second positions to lock the needle holder to, and to unlock the needle holder from, the outer tubular member. However, Shue et al does teach release means (segments [314][315]) on the needle holder (needle seat [31]) that are moveable between first and second positions to lock the needle holder to (Figures 4-7), and to unlock the needle holder from (Figures 8 and 11), the outer tubular member (barrel [2]) (column 5, lines 5-10)(column 6, lines 22-30). Release means [314][315] are released so that the needle holder [31] can retract with the end member [43] and move distally into the inner tubular member [4] (i.e. first position to second position).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the

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international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 2, 4-16, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Shue et al (US 6,921,386).

In regards to claims 1, 2, 15, 16, and 18, Shue et al teaches a catheter introducer (Figures 3-8 and 11) comprising:

- a. an outer tubular member (barrel [2])
- b. an inner tubular member (plunger [4])
- c. an end member/needle holding piston assembly (seal member [43]) having sealing means
- d. release means (sealing portion [434] and segment [433]) on the end member/needle holding piston assembly [43] and which is movable between a first position where the release means [434] locks the end member [43] to the inner tubular member [4] (Figures 4-6), and a second position where the release means [434] is unlocked from the inner tubular member [4] and allows the end member [43] to retract through the inner tubular member [4] (Figures 8 and 11) (column 5, lines 44-59)(column 7, lines 46-49 and 60-63)
- e. a needle holder (needle seat [31]), release means (segments [314][315]) on the needle holder and which is moveable between a first position where the release means locks the needle holder to the outer tubular member [2] (Figures 3-7), and a second position where the release means is unlocked from the outer tubular member (Figures 8 and 11) (column 5, lines 5-10) (column 6, lines 22-30)

From Applicant's specification and figures, the sealing means is a seal [31] (Page 14), the release means on the end member are fingers [32] (Page 15), and the release means on the needle holder are fingers [27] (Page 14).

In regards to claim 4, Shue et al teaches that the proximal end of the outer tubular member [2] is restricted in diameter with respect to the remainder of the outer tubular portion since the outer tubular member has stepped portions: larger-diameter segment [212, shoulder portion [213], and smaller diameter segment [211] (Figure 3).

In regards to claims 5 and 6, Shue et al teaches locking means (segment [226] in the form of a groove) on the outer tubular member [2] which lock the needle holder [31] to the outer tubular member (column 5, lines 5-10). *From Applicant's specification and figures, the gripping means is a recess/groove (Page 5).*

In regards to claims 7 and 8, Shue et al teaches that the end member [43] comprises a rear portion and a front portion, wherein the rear portion contains sealing means to enable the end member to sealingly and slidably engage the inner wall of the inner tubular member [4], as the rear portion is a component of the end member (seal member [43]), and the front portion contains the release means [434] (Figure 3).

In regards to claim 9, Shue al is silent about whether the release means [434] is resilient; however, since the release means [434] is an element of the elastomeric end member [43] (column 5, lines 46-48), it naturally follows that the release means is also elastomeric/resilient.

In regards to claim 10, Shue et al teaches that the at least one finger member [434], when in the first position (Figures 4-6), locks against the open proximal wall of the inner tubular member [4].

In regards to claim 11, Shue et al teaches that the at least one finger member [434] has an arrowhead configuration, since an arrowhead is defined as a “pointed head” and the at least one finger member [434] is pointed (Figures 3-7).

In regards to claim 12, Shue et al teaches that the needle holder [31] has a central body portion with a passageway to accommodate a puncture needle (needle cannula [32]) and the release means [314][315] being integral with the central body portion (Figure 3).

In regards to claim 13, Shue et al teaches that the release means comprises at least one finger [315] to enable the finger member to engage with release means [433] on the end member [43] (Figures 5-8)(column 6, lines 18-20). The release means also comprises another finger member [314].

In regards to claim 14, Shue et al teaches that the finger member [314] engages with a groove [226] in the outer tubular member [2] to releasably lock the needle holder [3] to the outer tubular member [20] (Figure 7)(column 5, lines 5-10).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shue et al, as applied to claim 2 above.

In regards to claim 3, Shue et al teaches captive means on the outer tubular member [2] and the inner tubular member [4], wherein the captive means function to restrain movement of the inner tubular member [4] relative to the outer tubular member [2]; the captive means comprise a rib segment [225] on the outer tubular member [2] and a projection (rib segment [425]) on the inner tubular member [4] (column 4, lines 52-55)(column 5, lines 41-42)(column 6, lines 9-11). However, claim 3 requires that the captive portion of the outer tubular member is a passageway and not a rib, as taught by Shue et al. But it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the captive portion of the outer tubular member of Shue et al to be a passageway instead of a rib, since it was known in the art that a projection/passageway engagement is stronger and will function more efficiently to restrain the movement of the inner tubular member relative to the outer tubular member than a projection/projection (rib/rib) engagement. *From Applicant's specification and figures, the captive means are a rib [24] and adjacent internal beads [25] forming a groove to fit the rib [24].*

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Shaw (US 5,817,058).

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/

Examiner, Art Unit 3767

11/06/2008

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767